UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO: ALL CLASS ACTIONS	Judge Patti B. Saris

TRACK 1 DEFENDANTS' JOINT MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT AGAINST ALL TRACK 1 DEFENDANTS

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Defendants respectfully submit this joint memorandum in opposition to Plaintiffs' Motion for Partial Summary Judgment against All Track 1 Defendants ("Plaintiffs' Motion"). Each Track 1 Defendant has simultaneously filed an opposition addressing the issues particular to that Defendant.

INTRODUCTION

Plaintiffs seek summary judgment on issues as to which they bear the ultimate burden of persuasion at trial. Under any circumstances, this is extraordinary; in this instance, it is entirely unjustifiable. Because Plaintiffs have the burden of persuasion at trial, they must make a *prima facie* showing in support of their motion for summary judgment that the defendants *could not* prevail at trial on any of those issues, which include virtually all of the issues addressed in the Defendants' submissions in support of their motions for summary judgment. Among many other things, Plaintiffs would have to persuade the Court as a matter of law that there is a legal definition of AWP that requires AWP to be within some defined proximity of provider acquisition costs. Then, as a factual matter, they must present evidence that would entitle them to a directed verdict that:

- There was a limitation on legally permissible spreads between AWPs of the subject drugs and provider acquisition costs of those drugs;
- The spreads between AWPs of the subject drugs and provider acquisition costs of those drugs during the 10+ years of the class period were larger than the law permitted;
- The defendants knew that their AWPs were required to be within some defined proximity of acquisition costs, and knew that their AWPs were further from acquisition costs than this defined proximity;
- The government did not know that the spreads between AWPs and acquisition costs of the subject drugs exceeded the legal limit; and

- If the government had known of the allegedly excessive spreads, the government would have altered the Medicare reimbursement rate for the subject drugs.[1]

These are but a few of the many issues on which the Plaintiffs' positions are not only controverted by competent evidence but also are demonstrably refuted by undisputed evidence. It is beyond credulity for Plaintiffs to ask the Court to find on the basis of the materials they submit that the Medicare statute requires AWPs to be within some definite percentage of provider acquisition costs when the uncontroverted record of government reports going back over a decade show spreads much larger than any the Plaintiffs would ask the court to find are "reasonable," and the Plaintiffs have not even provided the Court with properly measured acquisition costs of the subject drugs for the 10+ years at issue.

The Plaintiffs ask this much of the Court without having themselves done what the Court's rules require of every party moving for summary judgment: Assist the Court to evaluate the sufficiency of the factual basis for their motion by submitting a LR. 56.1 Statement that identifies record support for their assertions and arguments. In lieu of providing in their LR. 56.1 Statement citations to record sources for their assertions, Plaintiffs allude generally to Part III of their brief and the exhibits referenced in it – 116 pages of argument referring to 304 exhibits comprising 3,106 pages of materials. This is precisely what the First Circuit and this Court repeatedly have said warrants denial of motions for summary judgment. *See, e.g.*, *Corrada Betances v. Sea-Land Service, Inc.*, 248 F.3d 40, 43 (1st Cir. 2001); *Moore v. Marty Gilman, Inc.*, 965 F. Supp. 203, 207 n.1 (D. Mass. 1997); *Dale v. H.B. Smith Co.*, 910 F. Supp. 14, 20 (D. Mass. 1995).

[1] With respect to generic and multi-source drugs, which were reimbursed by Medicare based on a median AWP, Plaintiffs must also show that a change in the AWP of the subject products would have affected the median AWP for all generic and multi-source products of the kind and thus the reimbursement rate for all of those products.

ARGUMENT

I. PLAINTIFFS HAVE A HEAVY BURDEN ON SUMMARY JUDGMENT

Plaintiffs bear an exceptionally heavy burden when moving for summary judgment on issues as to which they bear the ultimate burden of persuasion at trial. Where, as here, "the *moving* party will bear the burden of persuasion at trial, that party must support its motion [for summary judgment] with credible evidence – using any of the materials specified in Rule 56(c) – that would entitle it to a directed verdict if not controverted at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 331 (1986); *accord Winnacunnet Co-op. School Dist. v. National Union Fire Ins. Co.*, 84 F.3d 32, 35 (1st Cir. 1996). The Plaintiffs "must establish every element [of their claims] as a matter of law such that no reasonable jury could return a verdict for the nonmovant." *Intn'l Ass'n of Heat and Frost Insulators and Asbestos Workers v. Absolute Ent'l Servs., Inc.*, 814 F. Supp. 392, 401 (D. Del. 1993). If and only if Plaintiffs can sustain that burden, "the burden then shifts to the nonmovant to proffer evidence. When the nonmovant does not bear the ultimate burden of proof at trial, the nonmovant may withstand summary judgment by coming forward with evidence sufficient to create a genuine issue of material fact as to any essential element of the movant's claim or defense." *Id.* at 402. In other words, Plaintiffs have the burden of proffering evidence in support of their motion that none of the defendants *could* prevail at trial on any of the issues as to which the Plaintiffs seek summary judgment. This they have not done, especially since Plaintiffs bear a particularly onerous burden of persuasion at trial on all Class 2 claims and those Class 1 claims that are governed by Massachusetts law. *Knapp Shoes, Inc. v. Sylvania Shoe Mfg. Corp.*, 72 F.3d 190, 200 (1st Cir. 1995) (holding that the Chapter 93A standard for liability is higher where transaction in question involves sophisticated entities); s*ee Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252-54 (1986) (holding that the burden of

persuasion at trial is the burden of persuasion that has to be met also on summary judgment).[2] But even if they had made this extraordinary *prima facie* showing – which they have not – their motion would still fail because the Defendants already have shown in their summary judgment submissions that they have compelling evidence not only to refute the Plaintiffs' contentions, but to support summary judgment in Defendants' favor.

II. PLAINTIFFS' MOTION SHOULD BE DENIED FOR FAILURE TO COMPLY WITH LR. 56.1

While bearing an unusually heavy burden, the Plaintiffs have failed to do what is minimally required of every party moving for summary judgment in this Court: provide in support of their motion

> a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried, with page references to affidavits, depositions, and other documentation.

LR. 56.1. Plaintiffs' Motion fails to comply with the express terms of LR. 56.1, and it commits the wrongs that the rule was intended to prevent. Rules such as LR. 56.1 are "'anti-ferret' rule[s]" the aim of which is "to make the parties organize the evidence rather than leaving the burden upon the district judge." *Alsina-Ortiz v. Laboy*, 400 F.3d 77, 80 (1st Cir. 2005). LR. 56.1 was created "in response to this court's concern that, absent such rules, summary judgment practice could too easily become a game of cat-and-mouse . . . . Such rules are a distinct improvement – and parties ignore them at their peril." *Gosselin v. Webb*, 242 F.3d 412, 414 n.2 (1st Cir. 2001). These rules are especially important in complex cases. *Dale*, 910 F. Supp. at 20. Providing an inadequate statement "generates a lot of dust," but "it does not further the goal of sharply focusing areas of dispute." *Key Trust Co. of Maine v. Doherty, Wallace, Pillsbury & Murphy, P.C.*, 811 F. Supp. 733, 734 n.2 (D. Mass. 1993).

[2] Since the government sets Medicare reimbursement rates, it is the sophistication of the government that maters for Chapter 93A analysis. (*See* Mem. Supp. Joint Mot. Summ. J. at 15-22.)

Plaintiffs here go to great lengths to "generate a lot of dust" by filing a LR. 56.1 Statement that contains 77 assertions without a single citation to the record. *See Alsina-Ortiz*, 400 F.3d at 80 (finding question whether similar rule "has been violated is . . . easily answered where the opponent . . . omits all record citations . . . ."); *Ruiz Rivera v. Riley*, 209 F.3d 24, 28 (1st Cir. 2000). It incorporates by reference citations to the record in Part III of their brief, which is comprised of 116 pages of argumentative narration, with references to 304 exhibits that aggregate 3,106 pages. Such a long and argumentative narrative, essentially incorporating the entirety of an overly long brief, does not and could not identify with specificity the material facts not in dispute, and it could not narrow the issues before the Court. *See, e.g.*, *Mass. Sch. of Law at Andover, Inc. v. American Bar Ass'n*, No. CIV.A.95-12320-MEL, 1997 WL 136240, at *1 n.3 (D. Mass. Mar. 3, 1997). Plaintiffs have demanded by their submissions, if they are to be taken seriously, that the Court and the Defendants sort through scores of pages of argument and thousands of pages of exhibits to identify the factual basis for the Plaintiffs' contentions. This is exactly the kind of "needle in a haystack" search that an "anti-ferret rule" like LR. 56.1 exists to prevent. *Morales v. A.C. Orssleff's EFTF*, 246 F.3d 32, 35 (1st Cir. 2001) (noting that "[f]orgiving plaintiffs' noncompliance with the local rule would undercut our efforts over the years to enlist counsel as aides to the court.").

III. PLAINTIFFS' INTERPRETATION OF "AWP" IS WRONG AS A MATTER OF LAW

Plaintiffs do not make recourse to proper tools of statutory and regulatory construction to support their argument that AWPs were supposed to be "reasonably" close to provider acquisition costs. As fully explained in the Memorandum of Law in Support of Track 1 Defendants' Joint Motion for Summary Judgment ("Joint Memorandum in Support of Summary Judgment"), the Court should defer the Health Care Financing Agency's ("HCFA's") (now the

Centers for Medicare and Medicaid Services ("CMS")) interpretation of the term AWP and Congress' understanding of the term when it used it in the statute. The operative regulation and the Medicare statute do not contain language that requires proximity between AWP and acquisition cost; no HCFA or CMS commentary, no congressional committee report, and no other item of legislative or regulatory history has words or meaning requiring such proximity. Indeed, it is undisputed that:

- At all relevant times, HCFA understood that AWPs were often significantly higher than provider acquisition costs, and that AWP was not a reliable indicator of the cost of a drug to physicians.[3]
- When HCFA first incorporated AWP into its regulations in 1991, it provided for reimbursement at the lower of AWP or estimated acquisition cost ("EAC"), demonstrating that there was understood to be a difference between the two.[4] HCFA then decided not to implement EAC.[5]
- In 1997, Congress explicitly rejected acquisition cost as a basis for reimbursement and instead decided to reimburse doctors for physician-administered drugs under Medicare Part B at the lesser of the actual charge or 95% of AWP.[6]
- When HCFA tried to circumvent congressional rejection of acquisition cost as a reimbursement basis by mandating that carriers use data on acquisition cost obtained from the Department of Justice, Congress objected and passed a statute imposing a moratorium on any effort to use any reimbursement benchmark other than 95% of AWP.[7]

The Plaintiffs offer nothing to support their legal position except a misplaced reliance on "plain meaning"; an excised portion of a 2002 statement from Thomas Scully, a former Administrator of CMS, which statement actually supports the Defendants' position; and

[3] (Mem. Supp. Joint Mot. Summ. J. at 4-6; Decl. of Lucy Fowler in Supp. of Defs.' 56.1 Stmt. in Supp. of Mem. Supp. Joint Mot. Summ. J. (Mar. 15, 2006) ("Fowler Decl."), Exs. 2-22, 24-28, 33-37, 40-44, 47.)
[4] (Mem. Supp. Joint Mot. Summ. J. at 9-10; Fowler Decl., Ex. 22.)
[5] (Mem. Supp. Joint Mot. Summ. J. at 10; Fowler Decl., Exs. 28-31, 36, 38.)
[6] (Mem. Supp. Joint Mot. Summ. J. at 6-7, 12-13; Fowler Decl., Ex. 44.) Plaintiffs have suggested that the term "actual charge" referred to the amount that the physician *paid* for the drug, but HCFA's implementing regulation makes clear that it is the physician's actual charge to patients, describing it as "the actual charge on the Medicare claim for benefits," which HCFA has noted "is often more than the amount Medicare approves." *See* 42 C.F.R. § 405.517(b) (Nov. 2, 1998); www.cms.hhs.gov/apps/glossary.
[7] (Mem. Supp. Joint Mot. Summ. J. at 8-9; Fowler Decl., Exs. 62, 64-70.)

guidelines published by the Office of Inspector General for the Department of Health and Human Services ("HHS-OIG") in 2003, which the Plaintiffs mischaracterize and are not in any event indicative of congressional or CMS intent.[8]

A. Plaintiffs' Reliance on the "Plain Meaning" of AWP is Misplaced

Plaintiffs suggest that the words "average wholesale price" must be interpreted in accordance with their "natural, ordinary and familiar meaning."[9] (Pls.' Mem. Supp. Mot. Partial Summ. J. against All Track 1 Defs. (hereinafter "Pls. Mem.") at 43.) Where, as here, however, a regulation or statute uses a term of art, those words should be "interpreted by reference to the trade or industry to which they apply." *Louisiana Pub. Serv. Comm'n v. F.C.C.*, 476 U.S. 355, 371-72 (1986). As the First Circuit recognized in *United States v. Lachman*, 387 F.3d 42, 53 (1st Cir. 2004), "there are instances where a statutory or regulatory term is a technical term of art, defined more appropriately by reference to a particular industry usage than by the usual tools of statutory construction."

As Professor Berndt has explained, knowledgeable participants in the health care industry have been well aware for many years that there is a substantial spread between actual costs and AWPs. Furthermore, there can be no doubt that both HCFA and Congress understood what the industry understood, *i.e.*, that the term AWP was unrelated to acquisition cost. In 1991, for example, when HCFA first promulgated a regulation basing reimbursement on AWP, it recognized that "the Red Book and other wholesale price guides substantially overstate the true cost of drugs." (Fowler Decl., Ex. 19.) In 1997, when Congress incorporated AWP into the

[8] Plaintiffs cite an article by Robert Ball, one of the architects of Medicare, who believed that reimbursement should be based on "the customary charges" of a physician. (Pls.' Mem. at 42.) The article and the position it espouses *contradict* the Plaintiffs' position: HEW's Task Force on Prescription Drugs noted in 1969 that "[i]n many cases . . . payment on the basis of customary charges would result in the program paying amounts for drugs that were far greater than the costs of the pharmacists in actually acquiring it." (Fowler Decl., Ex. 1 at 147.) That task force also observed that AWPs "rarely have any realistic relationship with actual acquisition cost." (*Id.* at 148.)

[9] Of course, the "definition" of AWP offered by Plaintiffs in the very same brief is below *wholesale* – so far below, in fact, that it is below average manufacturers' price.

statute governing Medicare reimbursement, it clearly understood that "AWP is not the average price actually charged by wholesalers to their customers . . . [r]ather, it is a 'sticker' price set by drug manufacturers and published in several commercial catalogs . . . ." (*Id.* Ex. 40.) In 2000, when HCFA tried to revert to a reimbursement scheme based on acquisition cost, Congress objected and reminded HCFA that it has been instructed "to base reimbursement for drugs on 95% of AWP, a term widely understood and indeed defined by department manuals to reference amounts reflected in specified publications." (Fowler Decl. ¶ 65.)

B. Statements of Thomas Scully Do Not Support the Plaintiffs' Interpretation

Plaintiffs attempt to use the words of Thomas Scully to define AWP as "the average price at which wholesalers sell drugs to their customers." (Pls.' Mem at 43-44.) Plaintiffs take Mr. Scully's words entirely out of context. In his statement Mr. Scully describes the Medicare reimbursement system – a system created by the federal government – as "seriously flawed." He describes the history of that system in great detail and explains that CMS (formerly HCFA) knew since at least 1991 – prior to the term's ever appearing in a regulation or statute – that AWP was not indicative of actual prices paid by physicians and pharmacies.[10] He goes on to say that CMS and its predecessor HCFA tried repeatedly to change the reimbursement rate to reflect "acquisition costs," but were opposed successfully in those efforts by physician groups and Congress. And, of course, HCFA and the HHS-OIG had been pointing out since the 1970s (in the context of the Medicaid program) that AWP did not represent actual acquisition costs.[11]

[10] For example, immediately following the statement Plaintiffs quote, Mr. Scully stated: "Traditionally, AWP has been based on prices reported by drug manufacturers and published in compendia such as the Red Book, which is published by Medical Economics Company, Inc. However, manufacturers and wholesalers increasingly give physicians and providers competitive discounts that reduce the actual amount the physician or provider actually pays for the drugs. . . . These discounts are not reflected in the published price and reduce the amount providers actually pay to levels far below those prices published in the Red Book." (Decl. of Steve W. Berman in Supp. of Plaintiffs' Mem. for Partial Summ. J. Against All Track 1 Defs., Ex. B.)

[11] (*See generally* Track 1 Defs.' 56.1 Stmt.)

Thus, when Mr. Scully stated that "AWP is intended to represent the average price at which wholesalers sell drugs to their customers," his comment certainly cannot be taken to mean that HCFA, CMS, or Congress intended it to have such a regulatory or statutory meaning from 1991 forward when he goes to such great lengths in the same statement to say that those same entities have known since 1991 that AWP *did not* represent an "average price."

Mr. Scully's statement is not in any event a reliable source of regulatory intent. What matters for regulatory interpretation are the "indications of the [agency's] intent at the time of the regulation's promulgation." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994); *see also SSM Rehab. Inst. v. Shalala*, 68 F.3d 266, 269-71 (8th Cir. 1995) (deferring to the original agency interpretation of a regulation notwithstanding a subsequently proposed amendment to the regulation that interpreted the regulation differently). Thus, because the Joint Memorandum in Support of Summary Judgment establishes conclusively that HCFA, CMS, and Congress did not intend AWP as used in the relevant regulations and statutes to be an actual average price, the Plaintiffs' mischaracterization of Mr. Scully's statement is simply beside the point of any proper understanding of the regulatory and legislative interpretation of the term AWP.

C. OIG Guidelines Do Not Support the Plaintiffs' Interpretation

1. Reliance on the Guidelines is Misplaced

Just as Plaintiffs attempt to use Mr. Scully to define AWP is misplaced, their attempt to rely on the HHS-OIG guidelines is similarly inappropriate. The HHS-OIG guidelines are not promulgated by CMS, HCFA, HHS, or Congress, who alone are responsible for the meaning of "AWP" and its use in the operative statute and regulation. The authority to promulgate rules and

regulations relating to the Medicare statute resides solely with the Secretary of HHS.[12] *See* 42 U.S.C. § 1302 (2006).

The HHS-OIG has no authority to make rules affecting the Medicare statute and plays no role in the rulemaking process used by CMS and HHS. The OIGs were established in the Inspector General Act of 1978 and given "the responsibility of conducting and supervising audits and civil and criminal investigations relating to [an] agency's operations." *United States Nuclear Regulatory Comm'n v. Fed. Labor Relations Auth.*, 25 F.3d 229, 233 (4th Cir. 1994) (citing Sen. Rep. No. 1071, 95th Cong., 2d Sess. 1 (1978)). The HHS-OIG has no statutory authority to make or interpret rules or regulations, and HHS does not have the power to delegate such authority to the HHS-OIG. *See Winters Ranch Partnership v. Viadero*, 123 F.3d 327, 334 (5th Cir. 1997) (holding that an agency "cannot convey to the [OIG] any of the agency's congressionally-delegated program operating responsibility"). Accordingly, what HHS-OIG says about a rule or regulation promulgated by the agency has no legal bearing on the meaning of that rule or regulation.[13] S*ee, e.g., Navarro v. Pfizer Corp.*, 261 F.3d 90, 99 (1st Cir. 2001) (holding that, where a division of an agency has been granted no rulemaking power, "its interpretive guidance is certainly not entitled to deference").[14]

2. Plaintiffs Have Mischaracterized the OIG guidelines

Not only do the Plaintiffs misplace reliance on the HHS-OIG's Guidelines, they also grossly mischaracterize them. The section containing the language upon which the Plaintiffs rely so heavily – "manufacturers' reported prices should accurately take into account price

[12] The Secretary of HHS has delegated its rulemaking authority to HCFA/CMS. *See* Stmt. of Org., Functions, and Delegations of Auth. for the Dep't of Health and Human Servs., Pt. F, 46 Fed. Reg. 13262-63 (1981).

[13] The Guidelines in this instance state that they "should not be viewed as mandatory" and are "intended to present voluntary guidance to the industry and not to represent binding standards for pharmaceutical manufacturers." OIG Compliance Program Guidance for Pharmaceutical Manufacturers ("HHS-OIG Guidelines"), 68 Fed. Reg. at 23731, 23731 (May 5, 2003).

[14] While HHS-OIG has no rulemaking or rule-interpreting authority, it is an investigative, fact-gathering agency, and in that capacity has played a significant role in informing HCFA, CMS, HHS and Congress about the marketplace reality that AWP is not a reliable indicator of actual acquisition cost.

reductions, cash discounts, free goods [and] rebates etc." – *does not refer to AWP*. The section addresses different subjects entirely, Average Manufacturer Price ("AMP") and Best Price ("BP"), which, unlike AWP, are prices that manufacturers report to HCFA and CMS as part of the *Medicaid* program.[15] Furthermore, the quoted language is qualified by the words: "Where appropriate . . . ."[16] HHS-OIG does not explain what it means by those words, but there is a strong federal policy supporting confidentiality for prices that reflect discounts, such as AMP and BP, and not requiring public prices to reflect discounts.[17] That is because federal agencies recognize that manufacturers will be less likely to offer discounts if they must be publicly disclosed.[18]

[15] The HHS-OIG addresses AWP in another section of the HHS-OIG Guidelines, 68 Fed. Reg. at 23736-37, in which he does not use anything like the language quoted out of context by the Plaintiffs or otherwise suggest that AWPs must reflect discounts.

[16] Moreover, Judge Woodlock aptly described AWP's application to the anti-kickback laws as "yeasty area" and questioned whether the federal anti-kickback law could ever be violated in a legal environment as "open-textured" as this. Tr. of Hr'g before Judge Woodlock, *United States v. Mackenzie*, CR-01-10350-DPW (D. Mass. June 24, 2004) at 6, attached as Ex. A.

[17] *See, e.g.*, 42 U.S.C. § 1396r-8 (2006) (Medicaid rebate statute providing for confidentiality of AMP and best price information), *amended* by Deficit Reduction Act of 2005, Pub. L. 109-171, 120 Stat. 4 (2006).

[18] (*See, e.g.,* Letter from Creighton et al. to Aghazarian (Sept. 7, 2004), attached to Decl. of Steven M. Edwards (Mar. 15, 2006), submitted in support of BMS's motion for summary judgment.)

CONCLUSION

For all the foregoing reasons, as well as those stated in the individual briefs of the Track 1 Defendants, the Track 1 Defendants respectfully request that Plaintiffs' Motion be DENIED.

Respectfully submitted,

THE TRACK 1 DEFENDANTS

/s/ Eric P. Christofferson
John T. Montgomery (BBO#352220)
Steven A. Kaufman (BBO#262230)
Eric P. Christofferson (BBO#654087)
Ropes & Gray LLP
One International Place
Boston, Massachusetts 02110-2624
(617) 951-7000

Attorneys for Schering-Plough Corporation and Warrick Pharmaceuticals Corporation

D. Scott Wise
Michael Flynn
Kimberley Harris
Davis Polk & Wardwell
450 Lexington Avenue
New York, NY 10017

Attorneys for AstraZeneca Pharmaceuticals LP

Steven M. Edwards
Lyndon M. Tretter
Hogan & Hartson, LLP
875 Third Avenue, Suite 2600
New York, NY 10022

Attorneys for the Bristol-Myers Squibb Co. and Oncology Therapeutics Network Corp.

Mark H. Lynch
Geoffrey E. Hobart (BBO #547499)
Ronald G. Dove, Jr.
Covington & Burling
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004-7566

Frederick G. Herold
Dechert LLP
1117 California Avenue
Palo Alto, CA 94304

Mark D. Seltzer (BBO #556341)
Holland & Knight LLP
10 St. James Ave.
Boston, MA 02116

Attorneys for SmithKline Beecham Corporation
d/b/a GlaxoSmithKline

William F. Cavanaugh, Jr.
Andrew D. Schau
Erik Haas
Patterson, Belknap, Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036 6710

Attorneys for the Johnson and Johnson Defendants

Dated: April 7, 2006

CERTIFICATE OF SERVICE

I hereby certify that on April 7, 2006, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ Eric P. Christofferson_____
Eric P. Christofferson